

REMARKS

Claims 1-9,11,13-17, 19-20,22,23,24,28,29 are pending. Claims 10,12,18 21, 25-27 have been cancelled. No claims have been withdrawn.

Support for the amendments to claims 1 and 30 are found in as-filed claim 18, and at page 5, lines 25-30 of the as-filed application. Support for claim 30 is further found in FIG. 3c.

Support for new claims 31 and 32 is found at page 6, lines 25-26 of the as-filed application. Support for new claim 33 is found in the Figures.

The amendment filed April 11, 2005 stands objected to under 35 USC 132(a) because it introduces new matter into the disclosure.

The Examiner took the position that whereas the original disclosure showed only one surface having a recess, claim 1 now recited "at least one of the upper and lower surfaces of the outer shell comprises a recess for receiving a pin". Applicants have amended claim 1 accordingly.

Claim 19 stands objected to as being of improper dependent form for failing to further limit the subject matter of the previous claim.

Applicants respectfully traverse. Whereas claim 1 covers instances wherein the recess can be either upon the upper or low surface, claim 19 restricts that recess particularly to the lower surface.

Claims 1-6,8,11,14-17,19,20,22-24,28 and 29 stand rejected under 35 USC 103 as being unpatentable over USP 6,402,785 (Zdeblick) in view of USP 6,802,863 (Lawson).

The Examiner took the position that Zdeblick discloses the invention except for the COF of at least 0.5, and that Lawson teaches providing a high COF to a surface of an

implant for immobility, and concluded that it would have been obvious to have provided the Zdeblick outer shell with a COF of at least 0.5, as taught by Lawson, for immobility.

Applicants respectfully traverse.

First, the present invention requires a non-resorbable one piece outer shell. This feature allows the outer shell act as a constraining force against the outward expansion of the core and so to more closely approximate the natural annulus fibrosus. In contrast, outer shell 152 (which has been set forth by the Examiner as representative of Zdeblick and is disclosed in FIG. 27 of Zdeblick) is a two-piece outer shell providing essentially no constraining force against the outward expansion of the core.

Moreover, as clearly shown in FIG. 27 of Zdeblick (which has been set forth by the Examiner as representative of Zdeblick), Zdeblick uses a screw to immobilize the upper and lower surfaces of the implant. Accordingly, the skilled artisan examining Zdeblick would understand that the upper and lower surfaces of that device were already fixed and so would have no motivation to include an extra characteristic (in this case, a high COF) in order to attain a desired attribute (in this case, immobility) because that attribute was already present in Zdeblick. In fact, because Zdeblick has already attained implant immobility via a different means, Zdeblick teaches away from the present invention.

Moreover, Applicants disagree with the Examiner's characterization of Lawson. Lawson use of a high COF for implant immobility relates only to providing intra-implant immobility (i.e., providing immobility between two components within the implant). When Lawson examines implant mobility vis-a-vis bone, Lawson moves in a different direction:

The replacement nucleus top must be biocompatible, exhibit a low coefficient of friction, have a smooth surface be resilient, and if possible radiolucent. (col. 4, lines 28-29). (emphasis supplied)

Thus, since the top of the Lawson implant articulates with bone, and Lawson teaches that the upper wall should have an upper surface having a low coefficient of friction, Lawson also teaches away from the present invention.

For these reasons, the above rejection should be withdrawn.

Claim 7 stands rejected under 35 USC 103 as being unpatentable over USP 6,402,785 (Zdeblick) in view of USP 6,802,863 (Lawson) and further in view of USP 5,545,229 (Parsons).

Since claim 7 depends from claim 1, the arguments provided directly above are applicable to claim 7. Accordingly, this rejection should be withdrawn.

Claim 9 stands rejected under 35 USC 103 as being unpatentable over USP 6,402,785 (Zdeblick) in view of USP 6,802,863 (Lawson) and further in view of USP 2004/0133278 (Marino).

Since claim 9 depends from claim 1, the arguments provided directly above are applicable to claim 9. Accordingly, this rejection should be withdrawn.

Claim 13 stands rejected under 35 USC 103 as being unpatentable over USP 6,402,785 (Zdeblick) in view of USP 6,802,863 (Lawson) and further in view of USP 6,554,867 (Joos).

Since claim 13 depends from claim 1, the arguments provided directly above are applicable to claim 13. Accordingly, this rejection should be withdrawn.

New claim 30 contains independent patentability. Lastly, again using FIG. 27 of Zdeblick, it is clear that Zdeblick passes a screw only through the outer shell of the

device. In contrast, claim 30 of the present invention requires that the pin pass through each of the core and outer shell.

New claims 31-2 contain independent patentability. Whereas Zdeblick discloses suitable shell materials as including relatively rigid materials such as stainless steel, polymers, carbon fiber, shape memory alloys, or porous material, claim 31 requires the outer shell to be an elastomeric material and claim 32 further particularizes the elastomer as polyurethane or silicone. These elastomers allow for the achievement of the desired hardness values disclosed in the present application that more closely mimic the elasticity of the natural annulus fibrosus than do the materials disclosed by Zdeblick. Therefore, these claims are allowable over the cited art.

Claim 33 contains independent patentability. Whereas Zdeblick at best discloses (in FIG. 24) a continuous outer shell, that shell in FIG. 24 does not completely enclose the core. Accordingly, it does not mimic the resistance provided by the annulus fibrosus. In contrast, the non-resorbable one piece outer shell of claim 33 has an inner surface that completely surrounds the central core, and so more closely mimics the annulus fibrosus.

In addition, the undersigned respectfully requests an interview with the Examiner before the next Office Action.

In addition, please provide any extensions of time which may be necessary and charge any fees which may be due to Deposit Account No. 10-0750, but do not include any payment of issue fees.

Should there be any remaining or further questions, the Examiner is requested to place contact the undersigned directly.

Respectfully submitted,

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